UREA

Berthelot/Colorimetric Method

IVD CE

PRODUCT CODE
CS017

INTENDED USE
For the quantitative determination of Urea in serum, plasma & urine.

CLINICAL SIGNIFICANCE
Urea is the end product of the protein metabolism. It is synthesized in the liver from the ammonia produced by the catabolism of amino acids. It is transported by the blood to the kidneys from where it is excreted. Increased levels are found in renal diseases, urinary obstructions, shock, congestive heart failure and burns. Decreased levels are found in liver failure and pregnancy

PRINCIPLE
Urease catalyses the conversion of urea to ammonia. In a modified Berthelot reaction, the ammonium ions react with a mixture of salicylate, hypochlorite and nitroprusside to yield a blue-green dye (Indophenol.) The intensity of this dye is proportional to the concentration of urea in the sample.

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2\,NH_3 + CO_2$$

$$NH_3 + \text{salicylate} + \text{hypochlorite} \xrightarrow{\text{Nitroprusside}} \text{2, 2-Dicarboxyindophenol}$$

REAGENT COMPOSITION
UREA REAGENT 1

Phosphate buffer	120 mmol/L
Sodium Salicylate	60 mmol/L
Sodium nitroprusside	5 mmol/L
EDTA	1 mmol/L
Urease	5 KU/L

UREA REAGENT 2

Phosphate buffer	120 mmol/L
Sodium Hydroxide	400 mmol/L
Sodium Hypochlorite	10 mmol/L

UREA STANDARD

Urea standard concentration	80 mg/dL or 13.3mmol/L

REAGENT PREPARATION
Reagents and standard are ready for use.

REAGENT STORAGE AND STABILITY
The reagents and standard are stable up to the expiry date when stored at 2 - 8° C.

SPECIMEN
Serum, Plasma (provided the anticoagulant used does not contain ammonium or fluoride) and urine 24hrs dilute (1 urine + 100 distilled water) Urea in serum is stable at 2-8° C for 3 days. Do not use lipemic samples.

PRECAUTION
- To avoid contamination, use clean laboratory wares.
- Serum specimens should be considered infectious and handled appropriately.

ASSAY

Wavelength	578 nm
Method	End point
Cuvette	1 cm light path
Temperature	20-25°C, or 37°C
Measurement	Against reagent blank

PROCEDURE

Pipette into cuvettes	Blank	Standard	Sample
Reagent-1	1000 µL	1000 µL	1000 µL
Sample	--	--	10 µL
Standard	--	10 µL	--
Mix and incubate for 5 minutes at 20-25°C or 3 minutes at 37°C			
Reagent-2	1000 µL	1000 µL	1000 µL
Mix and incubate for 10 minutes at 20-25°C or 5 minutes at 37°C Measure the absorbance of the sample (As) and the standard (Astd) against the reagent blank			

CALCULATION

$$\text{Urea Conc. (mg/dL)} = \frac{\Delta A \text{ sample}}{\Delta A \text{ standard}} \times 80 \text{ (Std.conc.)}$$

Urea (g/24 urine) = mg/dL X volume of 24-hour urine
To convert mg/dL to mmol/L divide by 6.01

LINEARITY
Serum values up to 400 mg / dL or 66.6 mmol/L. Urine values up to 40 g/1 or 6.66 mol/l, For higher values dilute sample 1+1 with distilled water, repeat assay and multiply the results by 2.

NORMAL RANGE

Serum	10 - 50 mg/dL	1.66 - 8.30 mmol/L
Urine 24hrs	10 – 35 g/L	1.66 - 5.83 mol/L

QUALITY CONTROL
All control sera with Urea values estimated by this method can be used.

NOTES
1- The test is not influenced by haemoglobin values up to 200 mg/dL or by bilirubin values up to 10mg/dL.
2- The standard contains sodium azide (0.1%) as preservative. Do not swallow and avoid contact with skin and mucous membranes.
3- Sodium hydroxide and hypochlorite in reagent 2 are irritants. In case of contact with eyes or mucous membranes wash immediately with water.
4- 1mg of urea corresponds to 0.467 mg of urea nitrogen.

SYMBOL ON LABELS

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

BIBILOGRAPHY

1- Berthelot A et at Clin. Chem 25 (2), 336, 1979
2- Tobacco, A et at , Clin, Chem 25 (2), 336 , 1979
3- Chaney A. L and Marbach E.P., Clin. Chem. 8.130 . 1962

Bio Research For Medical Diagnostics
Muslim Al Attar Street,P.O.Box:1235,
Amman-11953,Jordan
Tel:+962 64892525, Fax: +962 64892526,
www.bioresearch.com.jo

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany